

REMARKS

Claim 2 has been cancelled.

Claim 1 has been amended to recite “[c]hewable articles for animals, such as household dogs and cats, the articles being made from thermoplastically processable inulin or mixtures of inulin and/or oligofructans with thermoplastic polymers.” Support for this amendment is found in the specification at, for example, page 4, lines 24-28 and in original claim 2. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l) (8th ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments are respectfully solicited.

Rejection under 35 USC § 103:

Claims 1, 2, 4, 7, and 10-14 were rejected under 35 USC § 103(a) as being unpatentable over Leo, U.S. Patent No. 5,419,283 (“Leo”) in view of Van Loo *et al.*, U.S. Patent No. 6,500,805 or WO 98/52578 (“Van Loo”), Guttag, U.S. Patent No. 5,346,929 (“Guttag”), and Tomka, U.S. Patent No. 5,844,023 (“Tomka”). The Examiner stated that “the references and rejection[] is incorporated as cited in the previous office action.” (Paper No. 20060502 at 4).

For the reasons set forth below, the rejection, respectfully is traversed.

Leo discloses “[a] chew toy for animals [that] is molded into the shape of a familiar animal food item, such as a dog bone, from a polymer composition which is both edible and degradable. The composition is essentially comprised of a starch material and a degradable ethylene copolymer, preferably poly-ethylene-acrylic acid or

poly-ethylene, vinylalcohol.” (Abstract.) Leo further discloses that “[p]lasticizers and edible lubricants can also be added to the composition.” (*Id.*).

Van Loo discloses “the use of certain fructans, preferably certain inulins, for the manufacture of a composition for the prevention and/or treatment of colon cancer in non-bovine mammals.” (Col. 1, lines 9-12). Van Loo discloses that the composition can be incorporated into various foodstuffs, e.g., “a table spread, a dairy product such as e.g. a milk, a dairy dessert, a yoghurt, or a cheese, an alcoholic or non-alcoholic drink, a bakery product, a chocolate, an ice cream, a meat product, a fruit preparation, a confectionery product, a cereal product, a sauce, a soup, a snack, a dry mix, a meal replacer, a pet food, and the like.” (Col. 5, lines 43-51).

Guttag discloses “biodegradable plastic made from a combination of at least one synthetic plastic polymer, at least one natural polymer and a natural polymer attacking agent and articles made therefrom.” (Abstract). Guttag further discloses that “[t]he biodegradable plastic … can be used for the formation of articles, including but not limited to, bottles, toys, gloves, boxes, dishes, bowls, syringes, cups and diapers.” (Col. 3, lines 40-44). Guttag also discloses that “[t]he term ‘natural polymer’ … refers to polymers found in nature which are easily broken down by natural decay bacteria” and “includes … particles of starch, inulin, cellulose and wood.” (Col. 2, lines 33-35).

Tomka discloses a biologically degradable polymer mixture “which consists essentially of starch and at least one hydrophobic polymer.” (Abstract). “The hydrophobic polymer is in this connection at least substantially biologically degradable and thermoplastically processable and the mixture with the starch comprising a polymer phase mediator or a macromolecular dispersing agent so that the starch is present in

the mixture as disperse phase with the hydrophobic polymer as continuous phase, and the phase mediator or the dispersing agent is responsible for the molecular coupling of the two phases. As starch there is preferably used thermoplastic starch which has been prepared substantially with the exclusion of water by means of sorbitol or glycerol." (*Id.*)

In making the rejection of claim 1, the Examiner asserted that Leo discloses "an article for pets, specifically dogs and cats made from starch with a thermoplastic polymer." (Paper No. 20060502 at 2 and Paper No. 20050413 at 4). The Examiner acknowledged, however, that "Leo **does not show** an article made from inulin." (*Id.*) (emphasis added).

In making the rejection of claim 2, the Examiner asserted that Leo discloses "an article preferably made from a thermoplastically processable starch with thermoplastic polymer." (Paper No. 20050413 at 4). The Examiner also acknowledged, however, that "Leo **does not show** an article made from a thermoplastically processable inulin." (*Id.*) (emphasis added).

To fill the acknowledged gaps, the Examiner relied on Van Loo as disclosing inulin as "a functional food and can be present in any known food form including a pet food." (Paper No. 20060502 at 2 and Paper No. 20050413 at 4). In response to Applicants' remarks submitted March 13, 2006, the Examiner contended that "Van Loo teaches a fructan preferably inulin containing composition for the prevention and treatment of colon cancer in a non-bovine mammal (abstract)" and "it would have been obvious to one of ordinary skill in the art to modify Leo with Van Loo by incorporating inulin as an ingredient for cancer prevention." (Paper No. 20060502 at 2).

The Examiner further asserted that Applicant's argument that "neither Van Loo nor Tomka disclose that inulin or mixtures of inulin with thermoplastic polymers can be thermoplastically processed" is without merit because "product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." (*Id.* at 3).

The Examiner then asserted that "[w]ith regards to claims 4 and 10, Leo discloses in (col 2, lines 59-62), an article made from a degradable polymer consisting of starch." (Paper No. 20060502 at 4). The Examiner then asserted "[w]ith regards to claim 7, Leo discloses plasticizers including sorbitol and glycerol (col. 1, lines 49-54)" and "[w]ith regards to claim 13, Leo discloses a chew toy for animals in the shape of a dog bone (abstract)." (*Id.* at 4-5).

The Examiner also asserted "[w]ith regards to claim 11, Leo discloses a chew toy for animals comprising a starch material and a biodegradable thermoplastic polymer. The starch is present at a range from 10-40% by weight (Col 1 lines 33-35)." (Paper No. 20060502 at 4). The Examiner acknowledged, however, that "Leo fail[s] to disclose Inulin." (*Id.*). To fill the acknowledged gap, the Examiner relied on Guttag for "teach[ing] biodegradable plastic articles such as toys (Col 3 lines 40-44) comprising a synthetic plastic polymer, a natural polymer and a polymer attacking agent. The natural polymers are found in nature and are easily broken down by natural decay bacteria. It includes but is not limited to particles of starch, Inulin, cellulose and wood (Col 2 lines 31-34)." (*Id.*). The Examiner then contended that this disclosure in Guttag "suggests that starch and inulin are obvious equivalents as natural polymers and one of ordinary skill in the art would be able to utilize inulin in forming a toy/chewable article because it is easily broken down by natural decay bacteria." (*Id.*).

The Examiner also asserted “[w]ith regards to claim 12, Leo discloses an animal chew toy obtained by processing starch and a thermoplastic polymer in the presence of water or a plasticizer under extrusion coking conditions (Col 1 lines 33-41).” (*Id.*). The Examiner acknowledged, however, that “Leo fail[s] to disclose a temperature range for the process or inulin.” (*Id.*). To fill the acknowledged gap, the Examiner relied on Tomka as “teach[ing] a biodegradable polymer mixture consisting of starch and a thermoplastic polymer. The mixture is extruded at a range of temperatures from 80°C to 190°C (Col 15 lines 50-54),” and “Guttag [as] teach[ing] inulin and starch as obvious natural polymer equivalents.” (*Id.* at 4-5). The Examiner then contended that “[i]t would be obvious to one of ordinary skill in the art to modify Leo with teachings of Guttag and Tomka in order to provide a toy/chewable article because it is easily broken down by natural decay bacteria.” (*Id.* at 5).

The Examiner also asserted “[w]ith regards to claim 14, Leo discloses a chew toy for animals comprising a starch material and a biodegradable thermoplastic polymer. The thermoplastic blend is obtained by processing starch and thermoplastic polymer in the presence of water or plasticizer (Col 1 lines 33-37).” (*Id.*). The Examiner acknowledged, however, “Leo fail[s] to disclose Inulin.” (*Id.*). To fill the acknowledged gap, the Examiner relied on Guttag for “teach[ing] biodegradable plastic articles such as toys (Col 3 lines 40-44) comprising a synthetic plastic polymer, a natural polymer and a polymer attacking agent. The natural polymers are found in nature and are easily broken down by natural decay bacteria. It includes but is not limited to particles of starch, Inulin, cellulose and wood (Col 2 lines 31-34).” (*Id.*). The Examiner then contended that this disclosure in Guttag “suggests that starch and inulin are obvious equivalents as natural polymers and one of ordinary skill in the art would be

able to utilize inulin in forming a toy/chewable article because it is easily broken down by natural decay bacteria." (*Id.*).

Initially, we note that claim 2 has been cancelled, and claim 1 has been amended to recite "[c]hewable articles for animals, such as household dogs and cats, the articles being made from thermoplastically processable inulin or mixtures of inulin and/or oligofructans with thermoplastic polymers."

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *Glaug*, 62 USPQ2d at 1152. Moreover, in attempting to set forth a *prima facie* case for obviousness the Examiner is required to consider the claimed invention as a whole (*i.e.*, consider each and every limitation of the claimed invention). "In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983)." (MPEP § 2141.02, 8th ed., Rev. 2, May 2004, p. 2100-124 to 2100-125) (Emphasis original.)

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *KSR*

Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1731-32 (2007) (the obviousness “***analysis should be made explicit***” and the teaching-suggestion-motivation test is “***a helpful insight***” for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine “***must be based on objective evidence of record.***” *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added).

The rejection, however, again, contains no such showing. Instead, the Examiner has decided to, again, pick and choose from the disclosure of Leo and then combine that particular disclosure with that of particular disclosure chosen from Van Loo, Guttag, and Tomka. The Examiner has not provided ***any*** reason for ***why*** one would have chosen the particular disclosure relied upon by the Examiner in Leo, Van Loo, Guttag, and Tomka to the exclusion of all of the other disclosure in those references, and then would have distilled those particular disclosures to arrive at the claimed invention. That, however, was the Examiner’s burden.

The Examiner was required to demonstrate ***where*** in Leo there is a suggestion which would have “strongly motivated” one to modify the disclosure of Van Loo, Guttag, and Tomka and arrive at the applicants’ instantly claimed invention. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1986). The type of motivation which would have “***impelled***” one to do so (*Ex parte Levingood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes “***should***” be made. *Ex parte*

Markowitz, 143 USPQ 303, 305 (Bd. App. 1964). This the Examiner has not done.

Therefore, for this reason alone, the rejection should be withdrawn.

Moreover, the Examiner's conclusion that "it would have been obvious to one of ordinary skill in the art to modify Leo with Van Loo by incorporating inulin as an ingredient for cancer prevention" simply does not follow. (Paper No. 20060502 at 2). Leo discloses articles for pets made from starch and a degradable ethylene copolymer. As the Examiner has already admitted:

- (1) "**Leo does not show** an article made from inulin;"
- (2) "**Leo does not show** an article made from a thermoplastically processable inulin;" and
- (3) "**Leo fails to disclose** a thermoplastically processable inulin or mixtures of inulin." (Paper No. 20050413 at 4) (emphasis added).

And nothing in Van Loo, Guttag, or Tomka fills these acknowledged gaps. Neither Van Loo, Guttag, nor Tomka disclose that inulin or mixtures of inulin with thermoplastic polymers can be thermoplastically processed. The Examiner's reasoning that "it would have been obvious to one of ordinary skill in the art to modify Leo with Van Loo by incorporating inulin as an ingredient for cancer prevention" does not follow from the documents disclosures and is irrelevant to the claimed invention. Without any **suggestion** or **motivation** in **any** of the references that inulin is thermoplastically processable and that the thermoplastically processed articles have improved resistance to chewing and other mechanical properties rendering the articles attractive to animals, one of ordinary skill in the art would **not** be in a position to select inulin or mixtures of

inulin with thermoplastic polymers for the production of chewable articles as claimed.

For this further reason, the rejection should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness **must** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

Even if Leo, Van Loo, Guttag, and Tomka are properly combinable, which is not admitted, the proposed combination would not provide the article recited in independent claims 1 and 14. The rejection is based on the improper assumption that the property of inulin for preventing cancer (e.g., colon cancer) if administered with medicaments or functional foods (e.g., pet food) as disclosed by Van Loo and being biodegradable as disclosed by Guttag would suggest to one of ordinary skill in the art to modify Leo by incorporating inulin or using inulin in place of starch.

The Examiner's reasoning is flawed. A chewable toy is a molded article from which inulin cannot be released to prevent cancer. Therefore, it is **not** and **cannot be** made to be an equivalent to a functional pet food containing inulin, which is precisely what the Examiner has done. Moreover, to arrive at the currently claimed chewable article it is necessary to know the conditions which render inulin

thermoplastically processable, which is not disclosed by any of the cited documents. See *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005) (“Although published subject matter is ‘prior art’ for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art **must** enable a person of ordinary skill to make and use the invention.”) (emphasis added). In addition, missing from the cited documents, and the Examiner’s analysis, is a reasonable expectation of success of obtaining articles having the necessary resistance to chewing and other correlated mechanical properties (including, among others, the proper taste and aroma rendering the toy acceptable to pets), which is required to motivate one of skill in the art to use inulin in place of the starch disclosed in Leo.

A *prima facie* case of obviousness requires that the rejection describe with specificity **why** one skilled in the art would have combined the references to arrive at the claimed invention. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that ***the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.***”) (emphasis added). Here, the using of certain properties of inulin to motivate the Examiner’s combination (e.g., cancer prevention) of the cited references in an attempt to arrive at the claimed chewable article is based on an improper hindsight reconstruction of the claimed invention.

These same considerations apply to the rejection of claims 11, 12, and 14. To arrive at the chewable articles claimed, it is essential to thermoplastically process inulin. As discussed above, the conditions to render inulin thermoplastically

processable are not disclosed by the cited documents. Not knowing this renders the *motivation* to combine these cited documents an improper hindsight reconstruction of the claimed invention.

Guttag discloses a biodegradable plastic comprising three essential components: a synthetic polymer, a natural polymer, and a polymer attacking agent. Guttag further discloses that the natural polymer is easily broken down by natural decay bacteria, and the natural polymer "includes, but is not limited to, particles of starch, inulin, cellulose, and wood." (Col. 2, lines 31-34). Guttag discloses that the polymer attacking agent is a microorganism such as bacteria and fungi and is used in a quantity of about 1 wt% of the natural polymer. (Col. 2, lines 36-59). The biodegradable plastic of Guttag can be an article such as a sheet, a container, or a toy. (*Id.*).

In Guttag, the only discussion regarding articles made by processes requiring heat exposure, such as films, sheets, cups, and toys, is to use spore forming microorganisms in formulating the biodegradable plastic. (Col 3, lines 33-40). No mention is made regarding the thermoplastically processing of blends comprising inulin. Isolating inulin from the biodegradable plastic blends of Guttag, an essential component of which is a polymer attacking agent, *i.e.*, a microorganism, and to incorporate it into the chewable articles of Leo, or to use it in place of starch, is a reconstruction of the cited documents which is possible only by the Examiner's hindsight reconstruction of the claimed invention. *Dembiczak*, 50 USPQ2d at 1617. For this additional reason, the rejection should be withdrawn.

Application No.: 09/936,534

Amendment Dated: June 27, 2007

Reply to Office Action Dated: February 2, 2007

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 27, 2007.

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